

SECTION 4: APPENDICES**Appendix 4.1 Statement of Work**

Proposal Number: MTEC-20-12-COVID19-Diagnostics-084; W81XWH-15-9-0001

Organization: Fitbit, Inc.

Title: Early Detection of COVID-19 with Wearables

ACURO and/or HRPO approval needed: HRPO Approval Needed

Introduction/Background:

Fitbit is actively developing its most advanced (b) (4)

(b) (4) which together address MTEC's needs for a non-invasive, easy-to-use, (b) (4) that provides continuous physiological monitoring and early warning signals for COVID-19 infection. We believe that the combined offering of the Fitbit (b) (4) and COVID-19

(b) (4) can facilitate early quarantine and slow the spread of the disease. The prolonged incubation period and high transmissibility of COVID-19 are the factors that make early detection important in controlling the spread of the disease and that make (b) (4) an attractive solution for screening. A

(b) (4)

(b) (4)

Scope/Project Objectives

The project objective is to rapidly (b) (4)

(b) (4)

We hope to be able to quickly (b) (4)

(b) (4) Fitbit is asking for funding to expedite and scale the collection of the COVID-19 user-reported test results, to increase investment in machine learning algorithm development, and to fund a validation trial for a software as a medical device (SaMD) submission to the FDA to quickly be able to commercialize & scale. Our proposal is centered on 3 distinct phases:

- (1) **Development phase:** (b) (4)
- (2) **Validation Phase:** Trial to ready data set for Software as a Medical Device FDA approval.
- (3) **Commercialization Phase:** (b) (4)

(b) (4)

(b) (4)

Milestone Payment Schedule:

MTEC Milestone Number	Task Number	Significant Event/ Accomplishments	Due Date	Gov. Funds	Cost Share	Total Funding
1	N/A	Project Kickoff	(b) (4)	(b) (4)	(b) (4)	(b) (4)
2	1	Development Phase: Algo development commences	(b) (4)	(b) (4)	(b) (4)	(b) (4)
3	2	Development Phase: 1,000+ positive test results collected	(b) (4)	(b) (4)	(b) (4)	(b) (4)
4	3	Validation Phase: IRB submitted for validations study	(b) (4)	(b) (4)	(b) (4)	(b) (4)
5	N/A	Bimonthly Report 1 (b) (4) Technical and Business Reports)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
6	4	Validation Phase: IRB approved and prototypes ready	(b) (4)	(b) (4)	(b) (4)	(b) (4)
7	5	Achieve HRPO Approval	(b) (4)	(b) (4)	(b) (4)	(b) (4)
8	6	Validation Phase: 1st enrollment in validation study	(b) (4)	(b) (4)	(b) (4)	(b) (4)
9	N/A	Bimonthly Report 2 (b) (4) Technical and Business Reports)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
10	7	Validation Phase: Data collection complete	(b) (4)	(b) (4)	(b) (4)	(b) (4)
10	7	Commercial Phase: EUA submitted	(b) (4)	(b) (4)	(b) (4)	(b) (4)
11	8	Commercial Phase: Commercial SaMD technology ready for launch under EUA	(b) (4)	(b) (4)	(b) (4)	(b) (4)
12	N/A	Bimonthly Report 3 (b) (4) Technical and Business Reports)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
13	9	Commercial Phase: (b) (4) submission	(b) (4)	(b) (4)	(b) (4)	(b) (4)
14	10	Commercial Phase: Commercial SaMD technology ready for launch under (b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
15	N/A	Final Report	(b) (4)	(b) (4)	(b) (4)	(b) (4)
		Total		(b) (4)	(b) (4)	\$5,032,739

Section 3: Cost Share

Fitbit proposes a Cost Share. Fitbit will contribute costs associated with its internal resources (identified in Section 4.1 below). As identified in Figure 2 above, the Fitbit Cost Share totals

(b) (4) Fitbit seeks federal funds for the remainder of its Cost Proposal for a total of \$1,000,000 in federal funding.